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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/805,483	03/13/2001	Dennis W. Goupil	BioCure 190	3748

27029 7590 10/17/2002

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EXAMINER	
DI NOLA BARON, LILIANA	
ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 10/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/805,483	Applicant(s) GOUPIL ET AL.	
	Examiner Liliana Di Nola-Baron	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 August 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5,6,8-13 and 39-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,6,8-13 and 39-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other:

DETAILED ACTION

Receipt of Applicant's amendment, filed on August 29, 2002, and information disclosure statement, filed on May 17, 2002, is acknowledged.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1, 5, 6, 8-13 and 39-61 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5, 6, 8-14, 16, 18, 23, 24, 26-28, 50-61 and 63-69 of copending Application No. 09/804925. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are drawn to compositions comprising macromers having a polymeric backbone comprising units having a 1,2-diol or 1,3-diol structure and at least two pendant chains bearing crosslinkable groups, and methods of forming said compositions . The two sets of claims are largely coextensive.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

3. Claims 1, 5, 6, 8-13 and 39-61 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5, 6, 8-16, 18, 23, 24, 26-28 and 50-65 of copending Application No. 09/804963. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are drawn to compositions comprising macromers having a polymeric backbone comprising units having a 1,2-diol or 1,3-diol structure and at least two pendant chains bearing crosslinkable groups, and methods of forming said compositions . The two sets of claims are largely coextensive.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 39-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Műller alone or in view of Lally et al.

The claimed invention refers to a hydrogel biomedical article formed from macromers having a polymeric backbone comprising units having a 1,2-diol or 1,3-diol structure and at least two pendant chains bearing crosslinkable groups.

Műller provides a process for the production of mouldings, comprising crosslinking polymers having a 1,2- and /or 1,3-diol structure, such a s polyvinyl alcohol (PVA) containing a crosslinkable group and a modifier group, and mouldings made by said process (See e.g., col. 1, line 5 to col. 2, line 20). Műller includes biomedical and ophthalmic mouldings, mouldings used in surgery, such as heart valves and artificial arteries, films and membranes among the mouldings produced according to the invention (See e.g., col. 14, lines 50-64). The process disclosed by Műller includes introducing a solution comprising the prepolymer containing the crosslinkable group and the modifier into a mould, crosslinking and removing the moulding (See e.g., col. 15, line 56 to col. 16, line 29). Műller teaches that crosslinking can be done by free radical polymerization (See e.g., col. 17, lines 29-42). In the examples provided, Műller describes the synthesis of methacrylamidoacetaldehyde dimethyl acetal, acrylamidoacetaldehyde dimethyl acetal and 1-(2,2-dimethoxyethyl)3,4-dimethylpyrrole-2,5-dione (See examples 1, 2 and 7) and provides the method for the preparation of the products of the reaction of PVA with acetals or aldehydes (See example 15).

Thus, Műller provides the crosslinked polymers claimed in the instant application and articles made from said polymers, and provides the general teachings that said polymers can be used to form biomedical and ophthalmic devices. Műller does not specifically mention a contrast agent in the compositions of the invention.

Lally et al. provides a method of incorporating a reactive dye into a polymeric article used for films or membranes or ophthalmic applications (See e.g., col. 3, line 40 to col. 5, line 4). Lally et al. includes UV absorbing agents among the reactive dyes used in the invention (See e.g., col. 8,

lines 16-36). Preferred polymers used in the invention comprise crosslinked derivatives of PVA (See e.g., cols. 13-20). In Example 5, Lally et al. describes the preparation of crosslinkable PVA, comprising methacrylamidoacetaldehyde dimethyl acetal.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the teachings of Műller to device biomedical articles comprising crosslinked polymers and incorporate active agents into the polymers, as taught by Lally et al. Because of the teachings of Műller, that the polymers can be converted into biomedical devices, one of ordinary skill in the art would have a reasonable expectation that the compositions claimed in the instant application would be successful. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

6. Claims 1, 5, 6 and 8-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Műller in view of Thanoo et al. (J. Pharm. Pharmacol.).

The teachings of Műller have been summarized above. Műller is deficient in the fact, that it does not teach microspheres made from the polymers disclosed in the invention.

Thanoo et al. reports on the preparation of PVA microspheres crosslinked with glutaraldehyde and containing various drugs (See results and discussion).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the teachings of Műller to device microparticles incorporating active agents, as taught by Thanoo et al. to obtain cotrolled drug release microparticles. The expected result would have been a successful microparticle for the controlled release of drugs. Because of the teachings of Műller, that the polymers can be converted into biomedical devices, and the teachings of Thanoo et al., that microspheres for the controlled release of drugs can be made from crosslinked PVA, one of ordinary skill in the art would have a reasonable expectation that the compositions claimed in the instant application would be successful. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

7. Applicant's arguments filed on August 29, 2002 have been fully considered but they are not persuasive.

8. Applicant argues that the prior art does not teach or suggest microparticles made from the prepolymers of the invention. In response to said argument, it is noted that Thanoo et al. teaches that microspheres for the controlled release of drugs can be made from crosslinked PVA.

9. Applicant argues that the prior art does not teach or suggest that the prepolymers are crosslinked via redox initiated free radical polymerization. In response to said argument, it is noted that Műller includes free radical polymerization among the crosslinking mechanisms encompassed by the patent (See col. 17, lines 29-42).

10. In response to Applicant's argument, that the prior art does not teach biodegradable medical articles, it is noted that Műller provides biomedical and ophthalmic articles and devices used in surgery, such as heart valves and artificial arteries, films and membranes made from the same crosslinked polymers as claimed by Applicant. The burden is shifted to Applicant, to show that the biomedical articles disclosed by the prior art are not biodegradable.

Conclusion

11. Claims 1, 5, 6, 8-13 and 39-61 are rejected.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liliana Di Nola-Baron whose telephone number is 703-308-8318. The examiner can normally be reached on Monday through Thursday, 5:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1234/ 1235.

LDNB3

October 15, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600